Contact Details

Full Name: David Ronald Fitzpatrick USA telephone: (+1) 970-232-3318

USA Office: 155 E Boardwalk Drive Suite 400,

Fort Collins, Colorado 80525, USA Email: Biotechclaritycontact@gmail.com Web: www.biotechclarityconsulting.com

Position: Owner, Biotech Clarity Consulting LLC Australia telephone: (+61) 7-3853-5311 Australian Office: Brisbane Technology Park, 1 Clunies Ross Court, Eight Mile Plains,

Queensland 4113, Australia

Major Accomplishments

- Established a profitable biotech/pharma consulting business with an international clientele
- Strategic and scientific direction of a significant proportion of Amgen's Inflammation pipeline
- Helped advance >5 Amgen/Immunex projects into Ph1 trials, and >12 other projects towards development
- Experienced in both line (up to 50 staff) and project (discovery to early clinical development) management
- International research reputation in immunology, T lymphocytes, cytokines and epigenetics
- >20 years in biopharma, biomedical and veterinary research & development

Career Summary

Position/Degree	Company/Institution	Experience/Focus	Papers/Patents	Dates
Founder & Owner	Biotech Clarity Consulting LLC	Target, pathway, project, portfolio, partnering & investor analyses	Publications: #61-62	2006-on
Acting Director Associate Director Senior Staff Scientist Staff Scientist	Amgen Inc, Seattle WA, USA Immunex Corp, Seattle WA, USA	Oversight, principal investigator, or team member of >20 inflammation projects from discovery to preclinical to early clinical development of large & small molecule therapeutics Senior member of Dendritic Cell and Target Validation groups	Publications: #49-60 Patents: #5-8	2000-06
Senior Research Officer Research Officer Postdoctoral Fellow	Queensland Institute of Medical Research, Brisbane, Australia University of Western Australia Menzies Institute Darwin NT, Australia	Sole or joint principal investigator for research projects on regulation of T cell cytokines Joint principal investigator or team member for research projects on mesothelioma immunotherapy Human anti-chlamydia immunity	Publications: #20-48	1990-99
PhD Research Assistant MVSc	University of Saskatchewan, Canada CSL Ltd, Melbourne, Victoria, Australia University of Melbourne, Victoria, Australia	Bovine herpesvirus molecular biology, virology, immunology & vaccines Lead role in equine herpesvirus vaccine production & field trials Equine herpesvirus virology, immunology & vaccines	Publications: #1-19 Patents: #1-4	1977-89

Research & Professional Experience

- 2006-on Founder & Owner, Biotech Clarity Consulting LLC, Fort Collins CO USA & Brisbane QLD Australia.
- 2003-06 Associate/Acting Director, Amgen Incorporated, Seattle, Washington, USA.
- 2002-03 Research Scientist IV, Amgen Incorporated, Seattle, Washington, USA.
- 2001-02 Senior Staff Scientist, Immunex Corporation, Seattle, Washington, USA.
- 2000-01 Staff Scientist, Immunex Corporation, Seattle, Washington, USA.
- 1997-99 NHMRC Senior Research Officer, Queensland Institute of Medical Research, Australia.
- 1994-96 NHMRC Research Officer, Queensland Institute of Medical Research, Australia.
- 1991-93 Healy Postdoctoral Fellow, Department of Medicine, University of Western Australia.
- 1990-91 NHMRC Postdoctoral Fellow, Menzies School of Health Research, Darwin, Australia.
- 1985-89 PhD Student and Research Assistant, Veterinary Infectious Disease Organization, Saskatoon, Canada.
- 1984-85 Research Assistant, University of Melbourne and Commonwealth Serum Laboratories, Victoria, Australia.
- 1982-84 Master of Veterinary Science Student and Lab Demonstrator, University of Melbourne, Victoria, Australia.
- 1977-81 Bachelor of Veterinary Medicine and Surgery Student, Murdoch University, Perth, Western Australia.

Current Consulting Duties (2006-on)

- Client #1: Analyze and prioritize company's pipeline to accommodate lead compound's advance into clinical trials, design paths to IND for each preclinical project, devise next-generation discovery engine matched to company's focus, identify outsource options for discovery/preclinical/PhI activities, analyze blinded biomarker data from clinical trial samples, assist in recruiting new staff, assist in discussions and diligence with potential pharma and biotech partners, assist in R&D presentations to company's board and investors
- Clients #2-3: Identify emerging small molecule targets in Inflammation, Infectious Disease, Metabolic, Neurological Cardiovascular and Dermatology areas, analyze fit with company's technology, analyze competitive landscapes and partnering options, assist in presentation of top priorities to leadership group and board member
- Clients #4-5: Identify marketed and investigational drugs with problems amenable to client's new technology, conduct competitive landscape and potential market size briefings for each, evaluate product licensing opportunities, assist in presentation of top priorities to prospective venture capital investors
- Client #6: Evaluate preclinical Oncology programs, advise on target validation and lead antibody identification strategies, participate in joint steering team discussions with partner, analyze intellectual property landscape around selected cancer targets, edit and augment presentation materials for partnering
- Client #7: Subject matter expert for research and development educational materials on Rheumatology, Diabetes,
 Bone Diseases, and Multiple Sclerosis, with focus on mechanisms of action and clinical applications of
 currently marketed drugs versus company's investigational drugs
- Client #8: Preclinical experiment design and strategic recommendations for research funding applications in the area of influenza virus vaccine development
- Client #9: Design an array of target genes for the client's diagnostic technology and the aim of a marketed bloodbased test for use in specific niche areas of arthritis, inflammatory bowel disease and multiple sclerosis
- Clients #10+: Ad hoc target, technology and investment evaluations for venture capital companies and angel
- All Clients: Build and maintain proprietary database of key information on molecular targets of all marketed, investigational and emerging therapeutic agents and vaccines (currently n>2500)

Key Responsibility Areas (2000-2006)

- A. Analyze Inflammation therapeutic area projects and define new opportunities in relation to internal operating environment and external competitive landscape; establish Amgen's "Immuniverse" database of inflammation drug targets and pathways.
- B. Evaluate Inflammation and Oncology target and technology opportunities, including external inlicensing opportunities, internal intellectual property opportunities, and internal outlicensing opportunities.
- C. Advance Inflammation therapeutic area molecules towards clinical trials, including guidance on project strategy, experiment design, data analysis, and report preparation for regulatory filings.

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- D. Lead and expand the credible external reputation of Immunex/Amgen research via publications, patents, presentations and collaborations.
- E. Foster cross-site communication and integration within the research organization, between research and partner organizations, and across geographically dispersed sites.
- F. Provide mentoring and career development support for all scientific staff at all levels.

Institutional Committees

- 2003-06 Amgen Domestic and Foreign Patent Review Committees, Inflammation Licensing Evaluation Team, Extramural Research Assessment Team, Amgen Ventures Evaluation Team, Tularik Integration Team, Abgenix Integration Team, Amgen Foundation Grant Review Committee, Amgen Biotechnology Fellowship Lecturer, UW/Amgen/FHCRC Symposium Convenor
- 2000-02 Immunex Postdoctoral Fellow Mentor, Technology Assessment Team, Oncology Fellowship Lecturer 1995-99 Queensland Institute of Medical Research Computer Committee, Immunology Seminar Series Convenor, Grievance Referral Officer
- 1990-91 Joint Royal Darwin Hospital/Menzies School of Health Research Biosafety Committee, Radiation Safety Officer

Line Management, Mentoring & Supervision

- 2004-2005 Acting director of the ~40 person Immunological Systems department covering the areas of Immune Regulation, Cell Biology, Assay Technologies and Flow Cytometry.
- 2003-2004 Associate director of the ~20 person Immune Regulation research group, and >10 research projects from discovery to early clinical development.
- 1984-2002 Joint leader or key member of a series of small research teams, comprising 2-4 research associates, postdoctoral fellows and/or students, in Australia, Canada and the USA.
- 1987-2005 Supervisor, mentor or comentor for >30 scientists, postdoctoral fellows, PhD students, MSc students, Honours students, BMedSci students, and summer students. Details available on request.

Project Management

- 2003-2006 Oversight, principal investigator or team member of >20 Amgen Inflammation therapeutic area pipeline projects, ranging from discovery research to early clinical development
- 2000-2002 Principal investigator or team member of >10 Immunex research projects on discovery and validation of novel immunomodulatory molecules for cancer, autoimmune and/or inflammatory diseases
- 1984-1999 Principal investigator, joint leader or key member of a series of small research teams working on >20 grantfunded preclinical research projects in T cell immunology, cancer immunotherapy, and vaccine development

Continuing Education

- 2008 WIPO Advanced Course on Biotechnology and Intellectual Property, Geneva, Switzerland (on-line).
- 2005 Developing and Delivering Effective Messages, Seattle, Washington, USA.
- 2002 Situational Leadership II, Seattle, Washington, USA.
- 1998 Australian National Genomic Information Service Bioinformatics Course, Brisbane, Queensland, Australia.
- 1997 Grievance Referral Officer training, University of Queensland, Brisbane, Queensland, Australia.
- 1990 Radiation Safety Officer training, Northern Territory Dept Public Health, Darwin, Northern Territory, Australia.

Major Fellowships, Scholarships, Grants & Awards

- 2005 Amgen Development Award for R&D orientation and training materials.
- 2004 Amgen Development Award for dermatology biotechnology fellowship program.
- 2002 Immunex Applause Award for Leukine redaction/divestiture task force.
- 1999 International Union Against Cancer (UICC) Technology Transfer (ICRETT) Fellowship.
- 1997 Queensland Cancer Fund Travel Grant.
- 1992-94 Healy Medical Research Foundation Postdoctoral Fellowship.
- 1990-91 National Health & Medical Research Council Australian Postdoctoral Fellowship.
- 1985-89 Commonwealth Scholarship and Fellowship Plan Award (International PhD scholarship).
- 1982-84 Commonwealth Postgraduate Research Award (Masters scholarship).

Details for additional individual awards available on request.

1991-99 Awarded 12 research or equipment grants as chief investigator or co-chief investigator totalling >Aus\$1,000,000. Details available on request.

Degrees Awarded

1989 Doctor of Philosophy, University of Saskatchewan, Saskatchewan, Canada.

1984 Master of Veterinary Science (by research) University of Melbourne, Victoria, Australia.

1981 Bachelor of Veterinary Medicine & Surgery (1st Class), Murdoch University, Western Australia.

Areas of Research Experience & Interest

My reputation is based on >10 years experience in each of the following areas:

- Therapeutics and vaccine development: large and small molecule drugs for human inflammatory and autoimmune diseases, from discovery to early clinical trials; veterinary vaccine development, from design to field trials
- Immunology: Cellular and molecular biology of cytokines and their receptors; T cell differentiation; T cell and APC costimulatory molecule expression and signalling; regulation of innate immune responses and inflammation
- Molecular Cell Biology: Epigenetic regulation of gene expression; molecular and cellular determinants of differentiation decisions; cell surface receptor-ligand interactions

I am also experienced in research and/or development in the following areas:

- Allergic & Respiratory Diseases: asthma, atopic dermatitis, idiopathic pulmonary fibrosis, sarcoidosis
- Cancer: Mechanisms of tumor growth, silencing tumor suppressor genes, immune evasion, therapeutics issues
- Infectious Diseases: Mechanisms of pathogen immunosuppression and immunopathology, vaccine design

Society Memberships

2006-on Colorado Bioscience Association

2005-on AusBiotech - Australia's Biotechnology Industry Organisation

2004-on ADVANCE - Australian Professionals in America

2002-on Inflammation Research Association

2000-on American Association of Immunologists

1999-on American Association for the Advancement of Science

1998-on International Society for Interferon and Cytokine Research

1990-on Australasian Society for Immunology

Editorial Boards & Journal Reviews

2005-09 Associate Editor, Journal of Immunology

1999-on Editorial Board, Journal of Interferon and Cytokine Research

1995-on Reviewer for 18 journals including: Acta Haematologica, Arthritis & Rheumatism, Biotechniques, British Journal of Cancer, EMBO J, Gene, Human Immunology, Immunity, Immunology & Cell Biology, International Immunology, International Journal of Cancer, Journal of Experimental Medicine, Journal of Immunology, Journal of Gastroenterology & Hepatology, Journal of Interferon & Cytokine Research, Oncogene, Seminars in Immunology, Transplantation

Grant Reviews

1991-on Anti-Cancer Foundation of South Australia; Australian Research Council; Cancer Foundation of Western Australia; Cooperative Research Centre for Vaccine Technology, Australia; Dutch Arthritis Association, Netherlands; Harold Wetterberg Foundation, New Jersey, USA; Health Research Council of New Zealand; National Health & Medical Research Council of Australia; New South Wales Cancer Council, Australia; Wellcome Trust, UK; Women's and Children's Hospital Research Foundation, Adelaide, South Australia

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Publications (**Top research papers according to GoogleScholar citation rates)

- 62. Willis CR, Kennedy, MK, Brewer AW, Budelsky AL, Derry JM, Nelson LJ, Fitzpatrick DR & Blumberg H (2009) Exaggerated antibody responses in transgenic mice expressing CD30L on T cells. Manuscript submitted.
- 61. Schoenborn JR, Dorschner MO, Sekimata M, Santer DM, Fitzpatrick DR, Stammatoyonnapoulos JA & Wilson CB (2007) Comprehensive epigenetic profiling identifies multiple distal regulatory elements directing Ifng transcription. Nature Immunology 8:732-742.
- 60. Allakhverdi Z, Fitzpatrick D, Boisvert A, Baba N, Bouguermouh S, Sarfati M, Delespesse G (2006) Expression of CD103 identifies human regulatory T-cell subsets. Journal of Allergy & Clinical Immunology 118:1342-
- 59. Kersh EN, Fitzpatrick DR, Murali-Krishna K, Shires J, Boss JM, Speck SH & Ahmed R (2006) Rapid demethylation of the IFNgamma gene occurs in memory but not naïve CD8 T cells. Journal of Immunology 176:4083-4093.
- 58. Manton KJ, Douglas ML, Netzel-Arnett S, Fitzpatrick DR, Nicol DL, Boyd AW, Clements JA & Antalis TM (2005) Hypermethylation of the 5' CpG island of the gene encoding the serine protease testisin promotes its loss in testicular tumorigenesis. British Journal of Cancer 92:760-769.
- 57. Wilson CB, Makar KW, Shnyreva M & Fitzpatrick DR (2005) DNA methylation and the expanding epigenetics of T cell lineage commitment. Seminars in Immunology 17:105-119.
- 56. Oflazoglu E, Swart DA, Anders-Bartholo P, Jessup HK, Norment AM, Lawrence WA, Brasel K, Tocker JE, Horan T, Welcher AA & Fitzpatrick DR (2004) Paradoxical role of PD-L2 in Th2 mediated immune responses in vitro and in a murine asthma model. European Journal of Immunology 34:3326-3336.
- **55. Shnyreya M. Weaver WM. Blanchette M. Taylor SL. Tompa M. Fitzpatrick DR & Wilson CB (2004) Evolutionarily conserved sequence elements that positively regulate interferon-gamma expression in T lymphocytes. Proceedings of the National Academy of Sciences of the United States of America 101:12622-12627.
- **54. Makar KW, Perez-Melgosa M, Shnyreva M, Weaver WM, Fitzpatrick DR & Wilson CB (2003) Active recruitment of DNA methyltransferases regulates interleukin-4 in thymocytes and T cells. Nature Immunology 4:1183-1190.
- 53. Johnson BJ, Costelloe EO, Fitzpatrick DR, Haanen JB, Schumacher TN, Brown LE & Kelso A (2003) Differentiation of cytolytic CD8+ T cells with diverse perforin, granzyme and interferon-gamma expression patterns during murine influenza virus infection. Proceedings of the National Academy of Sciences of the United States of America 100:2657-2662.
- **52. Fitzpatrick DR & Wilson CB (2003) DNA methylation and demethylation in the regulation of genes, cells and responses in the immune system. Clinical Immunology 109:37-45.
- **51. Brawand P, Fitzpatrick DR, Greenfield BW, Brasel K, Maliszewski CR & De Smedt T (2002) Murine plasmacytoid pre-dendritic cells generated from Flt3 ligand-supplemented bone marrow cultures are immature APCs. Journal of Immunology 169:6711-6719.
- **50. Kelso A, Costelloe EO, Johnson BJ, Groves P, Buttigeig K & Fitzpatrick DR (2002) The genes for perforin, granzymes A, B and C and interferon-gamma are differentially expressed in single CD8+ T cells during primary activation. International Immunology 14:605-613.
- **49. Lee PP, Fitzpatrick DR, Beard C, Jessup HK, Lehar S, Perez-Melgosa M, Sweetser MT, Schlissel MS, Nguyen S, Cherry SR, Tsai JH, Tucker SM, Weaver WM, Makar K, Kelso A, Jaenisch R & Wilson CB (2001) A critical role for Dnmt1 and DNA methylation in T cell development, function and survival. Immunity 15:763-774.
- **48. Young J, Biden KG, Simms LA, Huggard P, Karamatic R, Eyre HJ, Sutherland GR, Herath N, Barker M, Anderson GJ, Fitzpatrick DR, Ramm GA, Jass JR & Leggett BA (2001) HPP1: a novel transmembrane protein-encoding gene commonly methylated in colorectal polyps and cancers. Proceedings of the National Academy of Sciences of the United States of America 98:265-270.
- **47. Bielefeldt-Ohmann H, Meyer M, Fitzpatrick DR & Mackenzie JS (2001) Dengue virus binding to human leukocyte cell lines: receptor usage differs between cell types and virus strains. Virus Research 73:81-89.
- 46. Fitzpatrick DR & Kelso A (1999) Nature versus nurture in T cell cytokine production. Journal of Leukocyte Biology 66:869-875.
- 45. Hogg N, Browning J, Howard T, Winterford C, Fitzpatrick D & Gobe G (1999) Apoptosis in vascular endothelial cells caused by serum deprivation, oxidative stress and TGF-beta. Endothelium 7:35-49.
- 44. Fitzpatrick DR & Bielefeldt-Ohmann H (1999) Transforming growth factor-beta in infectious disease: always there for the host and the pathogen. Trends in Microbiology 7:232-236.

- 43. Dottori M, Down M, Huettmann A, Fitzpatrick DR & Boyd A W (1999) Cloning and characterization of EphA3 gene promoter: DNA methylation regulates expression in hemopoietic tumor cells. Blood 94:2477-2486.
- **42. Fitzpatrick DR, Shirley K & Kelso A (1999) Cutting Edge: Stable epigenetic inheritance of regional interferongamma promoter demethylation in CD44^{high} CD8⁺ T lymphocytes. <u>Journal of Immunology</u> 162:5053-5057.
- **41. Fitzpatrick DR, Shirley KM, MacDonald LE, Bielefeldt-Ohmann H, Kay GF & Kelso A (1998) Distinct methylation of the interferon-gamma (IFN-γ) and interleukin-3 (IL-3) genes in newly-activated primary CD8⁺ T lymphocytes: regional IFN-y promoter demethylation and mRNA expression are heritable in CD44^{high} CD8⁺T cells. Journal of Experimental Medicine 188:103-117.
- 40. Egerton M, Fitzpatrick DR & Kelso A (1998) Activation of the extracellular-signal regulated kinase (ERK) pathway is differentially required for T cell antigen receptor-stimulated production of six cytokines in normal T lymphocytes. International Immunology 10:223-229.
- 39. Fitzpatrick DR & Kelso A (1998) Independent regulation of cytokine genes in T cells: the paradox in the paradigm. Transplantation 65:1-5.
- 38. Bielefeldt-Ohmann H, Beasley DW, Fitzpatrick DR & Aaskov JG (1997) Analysis of a recombinant dengue-2 virus-dengue-3 virus hybrid envelope protein expressed in a secretory baculovirus system. Journal of General Virology 78:2723-2733.
- 37. Bielefeldt-Ohmann H & Fitzpatrick DR (1997) High-efficiency T-vector cloning of PCR products by forced Atagging and post-ligation restriction enzyme digestion. Biotechniques 23:822-826.
- 36. Fitzpatrick DR, Egerton M & Kelso A (1997) Regulation of cytokine genes. In: I.M. Roitt & P.J. Delves (Eds) Encyclopedia of Immunology, Second Edition. Academic Press, London. Vol 2, p699-702.
- **35. Marzo AL, Fitzpatrick DR, Robinson BW & Scott B (1997) Antisense oligonucleotides specific for transforming growth factor beta2 inhibit the growth of malignant mesothelioma both in vitro and in vivo. Cancer Research 57:3200-3207.
 - 34. Egerton M, Fitzpatrick DR, Catling AD & Kelso A (1996) Differential activation of T cell cytokine production by the extracellular-signal regulated kinase signalling pathway. European Journal of Immunology 26:2279-2285.
 - 33. Bielefeldt-Ohmann H, Jarnicki AG & Fitzpatrick DR (1996) Molecular pathobiology and immunology of malignant mesothelioma. Journal of Pathology 178:369-378.
 - 32. Raggo C, Fitzpatrick DR, Babiuk LA & Liang X (1996) Expression of bovine interleukin-1beta in a bovine herpesvirus-1 vector: in vitro analysis. Virology 221:78-86.
 - 31. Jarnicki A, Fitzpatrick DR, Robinson BW & Bielefeldt-Ohmann H (1996) Altered CD3 chain and cytokine gene expression in tumor infiltrating lymphocytes during development of mesothelioma. Cancer Letters 103:1-9.
 - 30. Fitzpatrick DR, Manning LS, Musk AW, Robinson BW & Bielefeldt-Ohmann H (1995) Potential for cytokine therapy of malignant mesothelioma. Cancer Treatment Reviews 21:273-288.
 - 29. Fitzpatrick DR & Kelso A (1995) Dissociated expression of granulocyte-macrophage CSF and IL-3 in short-term T cell clones from normal mice. Journal of Immunology 155:5140-5150.
 - 28. Bielefeldt-Ohmann H, Marzo A, Himbeck R, Robinson BW & Fitzpatrick DR (1995) IL-6 Involvement in mesothelioma pathobiology: inhibition by interferon-alpha immunotherapy. Cancer Immunology Immunotherapy 40:241-250.
 - 27. Fitzpatrick DR. Peroni DJ & Bielefeldt-Ohmann H (1995) The role of growth factors and cytokines in the tumorigenesis and immunobiology of malignant mesothelioma. American Journal of Respiratory Cell and Molecular Biology 12:455-460.
 - 26. Bielefeldt-Ohmann H, Fitzpatrick DR, Marzo AL, Jarnicki AG, Musk AW & Robinson BW (1995) The potential for interferon-alpha-based therapy against malignant mesothelioma: assessment in a murine model. Journal of Interferon and Cytokine Research 15:213-223.
 - 25. Staton JM, Dench JE, Currie B, Fitzpatrick DR, Himbeck RP, Allen R, Bruce J, Robinson BW & Bielefeldt-Ohmann H (1994) Expression and immune recognition of stress proteins in sarcoidosis and other chronic interstitial lung diseases. Immunology and Cell Biology 73:23-32.
 - 24. Bielefeldt-Ohmann H, Fitzpatrick DR, Marzo AL, Jarnicki AG, Himbeck RP, Davis MD, Manning LS & Robinson, BW (1994) Pathobiology and immunobiology of malignant mesothelioma: characterisation of tumor-infiltrating leukocytes and cytokine production in a murine model. Cancer Immunology Immunotherapy 39:347-359.
- **23. Fitzpatrick DR, Bielefeldt-Ohmann H, Jarnicki AG, Marzo AL, Himbeck RP & Robinson BW (1994) Transforming growth factor-beta: antisense RNA-mediated inhibition affects anchorage-independent growth, tumorigenicity and tumour-infiltrating T-cells in malignant mesothelioma. Growth Factors 11:29-44.
- 22. Garlepp MJ, Fitzpatrick DR, Mutsaers SE, Bielefeldt-Ohmann H, Davis MR & Robinson BW (1993) Mesothelioma: recent studies of growth regulation. In: G.A. Peters & B.J. Peters (Eds.) Sourcebook on Asbestos Diseases, Volume 7. Butterworth, Salem, New Hampshire, p201-218.

- 21. Fitzpatrick DR, Wie J, Webb D, Bonfiglioli R, Gardner ID, Mathews, JD & Bielefeldt-Ohmann H (1991) Preferential binding of Chlamydia trachomatis to subsets of human lymphocytes and induction of interleukin-6 and interferon-gamma. Immunology and Cell Biology 69:337-348.
- 20. Fitzpatrick DR, Bielefeldt-Ohmann H & Gardner ID (1991) Immune responses to Chlamydia trachomatis infections. Today's Life Science 2:18-23.
- 19. Fitzpatrick DR & Bielefeldt-Ohmann H (1991) Mechanisms of herpesvirus immuno-evasion. Microbial Pathogenesis 10:253-259.
- 18. van Drunen Littel-van den Hurk S, Parker MD, Fitzpatrick DR, van den Hurk JV, Campos M, Babiuk LA & Zamb TJ (1991) Structural, functional and immunological characterisation of bovine herpesvirus 1 glycoprotein gl expressed by recombinant baculovirus. Virology 190:378-392.
- 17. Liang X, van Drunen Littel-van den Hurk S, Babiuk LA, Fitzpatrick DR & Zamb TJ (1991) Bovine herpesvirus type 1 attachment to permissive cells is mediated by its major glycoproteins, gl, glll, and glV. <u>Journal of Virology</u> 65:1124-1132.
- 16. van Drunen Littel-van den Hurk S, Parker MD, Fitzpatrick DR, Zamb TJ, van den Hurk JV, Campos M, Harland, R & Babiuk LA (1991) Expression of bovine herpesvirus-1 (BHV-1) glycoprotein gIV by recombinant baculovirus and analysis of its immunogenic properties. Journal of Virology 65:263-271.
- **15. Tikoo SK, Fitzpatrick DR, Babiuk LA & Zamb TJ (1990) Molecular cloning, sequencing and expression of functional bovine herpesvirus 1 glycoprotein gIV in transfected cells. <u>Journal of Virology</u> 64:5132-5142.
 - 14. Fitzpatrick DR, Snider M, McDougall L, Beskorwayne T, Babiuk LA, Zamb TJ & Bielefeldt Ohmann H (1990) Molecular mimicry: a herpesvirus glycoprotein antigenically related to a cell surface glycoprotein expressed by macrophages, polymorphonuclear leukocytes, and platelets. Immunology 70:504-512.
 - 13. Parker MD, Cox GJ, Yoo D, Fitzpatrick DR & Babiuk LA (1990) The haemagglutinin of bovine coronavirus exhibits significant similarity to the haemagglutinin of type C influenza virus. Advances in Experimental Medicine and Biology 276:103-108.
 - 12. Fitzpatrick DR, Zamb TJ & Babiuk LA (1990) Expression of bovine herpesvirus type 1 glycoprotein gl in transfected bovine cells induces spontaneous cell fusion. Journal of General Virology 71:1215-1219.
 - 11. Fitzpatrick DR, Redmond MJ, Attah-Poku SK, van Drunen Littel-van den Hurk S, Babiuk LA & Zamb TJ (1990) Mapping of 10 epitopes of bovine herpesvirus type 1 glycoproteins gl and glll. Virology 176:145-157.
 - 10. Fitzpatrick DR (1989) Immunobiology of Bovine Herpesvirus Type 1 Glycoproteins gl and glll. PhD thesis. University of Saskatchewan.
 - 9. Parker MD, Cox GC, Deregt D, Fitzpatrick DR & Babiuk LA (1989) Cloning and in vitro expression of the gene for the E3 haemagglutinin glycoprotein of bovine coronavirus. <u>Journal of General Virology</u> 70:155-164.
 - 8. Fitzpatrick DR, Babiuk LA & Zamb TJ (1989) Nucleotide sequence of bovine herpesvirus type 1 glycoprotein glll, a structural model for glll as a new member of the immunoglobulin superfamily, and implications for the homologous glycoproteins of other herpesviruses. Virology 173:46-57.
 - 7. Bielefeldt Ohmann H, Campos M, Fitzpatrick DR, Rapin N & Babiuk LA (1989) A neutrophil derived antiviral protein: induction requirements and biological properties. Journal of Virology 63:1916-1923.
 - 6. Fitzpatrick DR, Zamb TJ, van Drunen Littel-van den Hurk S, Parker M, Babiuk LA & Lawman MJ (1988) Expression of recombinant bovine herpesvirus 1 glycoproteins gl and glll in transfected murine cells. Journal of Virology 62:4239-4248.
 - 5. Studdert MJ, Fitzpatrick DR, Browning GF, Cullinane AA & Whalley JM (1986) Equine herpesvirus genomes : heterogeneity of naturally occurring type 4 isolates and of a type 1 isolate after heterologous cell passage. Archives of Virology 91:375-381.
 - 4. Studdert MJ & Fitzpatrick DR (1985) Molecular epidemiology and pathogenesis of equine herpesvirus type 1 (equine abortion), type 4 (equine rhinopenumonitis) and type 3 (equine coital exanthema). In: "Veterinary Virus Diseases in SE Asia and the West Pacific" Editor A.J. Della-Porta. Academic Press, Sydney, Australia.
 - 3. Fitzpatrick DR (1984) Immunologic Relationships Between Equine Herpesvirus Type 1 and Type 4. MVSc thesis. University of Melbourne.
 - 2. Studdert MJ, Fitzpatrick DR, Horner GW, Westbury HA & Gleeson LJ (1984) Molecular epidemiology and pathogenesis of some equine herpesvirus type 1 (equine abortion virus) and type 4 (equine rhinopneumonitis virus) isolates. Australian Veterinary Journal 61:345-348.
 - 1. Fitzpatrick DR & Studdert MJ (1984) Immunologic relationships between equine herpesvirus type 1 (equine abortion virus) and type 4 (equine rhinopneumonitis virus). American Journal of Veterinary Research 45:1947-1952.

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Patents

- 9. Tocker JE, Peschon JJ & Fitzpatrick DR. Methods of using IL-17 receptor A antibodies. <u>US 2008/0219979</u>.
- 8. Tocker JE, Peschon JJ, **Fitzpatrick DR**, Smothers JF, Mehlin C & Lim AC. IL-17 receptor A antigen binding proteins. WO 2008/054603.
- 7. Comeau MR & Fitzpatrick DR. Compositions and methods for treating fibrotic disorders. WO 2006/083947.
- 6. Comeau MR, DeSmedt T & **Fitzpatrick DR**. Methods and compositions for treating allergic inflammation. WO 2006/023791.
- 5. **Fitzpatrick DR**, Roux ER, Maliszewski CR & Peschon JJ. Method for generating immortal dendritic cell lines. Australian Patent AU2002/230693; WO 2002/048167.
- 4. Babiuk LA, van Drunen Littel-van den Hurk S, Zamb T & **Fitzpatrick DR** (1999) Recombinant bovine herpesvirus type 1 polypeptides and immunoassays. <u>U.S. Patent 5,879,895</u>.
- 3. Babiuk LA, van den Hurk S, Zamb T & **Fitzpatrick DR** (1999) Vaccine comprising nucleotide sequences encoding bovine herpesvirus type-1 gl, glll and glV. <u>U.S. Patent 5,858,989</u>.
- 2. Babiuk LA, van den Hurk S, Zamb T & **Fitzpatrick DR** (1996) Nucleotide sequences encoding recombinant bovine herpesvirus type-1 gl, glII and glV polypeptides. <u>U.S. Patent 5,585,264</u>.
- Babiuk LA, van Drunen Littel-van den Hurk S, Zamb T & Fitzpatrick DR (1993) Recombinant bovine herpesvirus type 1 polypeptides and vaccines. <u>U.S. Patent 5,151,267</u>; <u>Canadian Patent 1,338,069</u>; <u>European Patent 0618814</u>.

Major Presentations

- MP14+. Client-confidential research & development presentations to board members, potential investors, and potential corporate partners. This includes to representatives from Pfizer, Merck, Novartis, Roche, Amgen, Lilly, Boehringer, Eisai, Bayer, MerckSerono and a number of other major companies.
- MP13. "Biomarker Discovery & Validation in Laboratory Animal Models". Lecture in Advanced Laboratory Animal Medicine course for veterinary pathology residents. Colorado State University, November 2007.
- MP12. "The Immuniverse: a Database of Amgen Molecules, Licensing Opportunities, Competitor Drugs, & Potential Targets". Inflammation Therapeutic Area strategy retreat. Amgen Thousand Oaks CA, February 2006.
- MP11. "Inflammation Pipeline Diversification and Differentiation". Inflammation Therapeutic Area Review presentation to Research Review Board. Amgen Thousand Oaks CA, November 2004.
- MP10. "Introduction to Biotechnology and Large-Molecule Therapeutics". Amgen Biotechnology Fellowship lecture to rheumatology and dermatology professionals. Seattle WA, September 2004.
- MP9. "Regulation of gene expression in T cells: new insights into key epigenetic determinants". Invited symposium presentation. 33rd Annual Scientific Meeting of the Australasian Society for Immunology, Perth, Western Australia. December 2003.
- MP8. "Immunex Molecules & Dendritic Cells in Cancer Immunotherapy". Immunex New England Business Unit presentation to oncology residents. Seattle WA, August 2001.
- MP7. "Epigenetics, gene discovery and immunological memory". Invited institute seminar. <u>Immunex Corporation</u>, Seattle, Washington, USA, October 1999 (All expenses paid).
- MP6. "Epigenetics of T cell cytokine gene expression". Invited institute seminar. <u>Centenary Institute of Cancer Medicine</u> & Cell Biology, Sydney, New South Wales, Australia, July 1998 (All expenses paid).
- MP5. "Regulation of cytokine expression in T lymphocytes: cells, signals, and genes". Invited symposium presentation. 24th Annual Meeting of the American Society of Transplant Surgeons, Chicago, Illinois, USA, May 1998 (All expenses paid).
- MP4. "Epigenetics of T cell cytokine gene expression". Invited symposium presentation. <u>27th Annual Scientific Meeting of the Australasian Society for Immunology</u>, Perth, Western Australia, December 1997.
- MP3. "Epigenetics of T cell cytokine gene expression". Invited institute seminar. <u>Immunex Corporation</u>, Seattle, Washington, USA, October 1997 (Part expenses paid).
- MP2. "Uncoordinated T cells". Invited symposium presentation. 25th Annual Scientific Meeting of the Australasian Society for Immunology, Gold Coast, Queensland, Australia, December 1995.
- MP1. "Analysis of the roles of transforming growth factor-beta in the tumorigenesis of malignant mesothelioma".

 Workshop presentation. Annual Meeting of the Clinical Oncology Society of Australia, Perth, November 1993.

Details for >40 other presentations and conference abstracts available on request.

Background

<u>2006-on</u>: In June 2006 I left full-time employment with Amgen and started the consultancy business Biotech Clarity Consulting LLC (<u>www.biotechclarityconsulting.com</u>). The business has served more than 20 clients in 5 countries – USA, Canada, UK, Australia & China – with a clientele ranging from venture capital firms to startup companies to publicly listed biotechs to big pharma. It provides biotechnology and pharmaceutical drug development services ranging from discovery to preclinical to translational to early clinical trials. It often provides consulting services together with Helle Bielefeldt-Ohmann of Biohm Discovery Research Pathology (<u>www.biohmpathology.com</u>), Mike Gresser of Clarity Therapeutics Consulting (<u>www.claritytherapeuticsconsulting.com</u>), and other experts as required.

2004-06: In July 2004, after Dr. Charlie Maliszewski's retirement, I assumed Acting Director responsibilities for the Immunological Systems Department. In September 2004 I was promoted to Associate Director level II, reporting to the Vice-president of Inflammation Research, Dr. Mike Gresser. In mid-2005 the ImmSys Department comprised 37 staff in the areas of Immune Regulation, Cell Biology, and Assay Technologies. It included 2 associate directors, 16 scientists, 8 associate scientists, 8 research associates and 1 administrative coordinator. Their work included >20 research projects, ranging from discovery to early clinical development, in the areas of arthritis, asthma, psoriasis, scleroderma and other diseases. In September 2005, I departed Seattle in the context of an employment opportunity for my spouse in Colorado. An extension of my Amgen position was arranged, on the unprecedented basis of telecommuting and travel from Colorado, with a mix of continuing duties plus new special projects. This began in November 2005 and continued to June 2006 with daily telecommuting and fortnightly travel to each of the four Amgen research sites. I effectively served as a consultant and mentor with a roving commission: vertically across the Inflammation therapeutic area projects and people, and horizontally across the interactions with partner organizations.

2000-03: In March 2000 I moved to Seattle and joined Dr. Charlie Maliszewski's Dendritic Cell Biology Group in Immunex Corporation as a Staff Scientist. In both 2000 and 2001 I was nominated for scientific achievement awards and in June 2001 I was promoted to Senior Staff Scientist. In July 2002, Immunex was acquired by Amgen and my position was converted to Research Scientist level IV with group leader responsibility for Immune Regulation. In February 2003 I was promoted to Associate Director level I with additional duties. The Immune Regulation Group peaked at 22 staff: 7 research scientists, 3 associate scientists, 10 research associates and 2 postdoctoral fellows. This group worked on >10 research projects, ranging from discovery to preclinical development.

1994-99: In January 1994 I moved to Brisbane, Queensland, and joined the Transplantation Biology Unit of Dr. Anne Kelso in the Queensland Institute of Medical Research to study the regulation of T cell cytokines. I was promoted to Senior Research Officer level in November 1996 as the chief investigator on a NHMRC project grant application. My research focussed on the molecular regulation of cytokine gene expression in T cells, in settings relevant to infection, transplantation and cancer. Collaborations included several locally in Queensland, interstate in Australia, and internationally in the USA. Cosupervisory duties covered 1 postdoctoral fellow, 2 research assistants and 1 PhD student. My work on DNA methylation was acknowledged internationally via publications, invited presentations, and job offers.

1991-93: In July 1991, I returned home to Perth to take up a postdoctoral fellowship in the laboratory of Dr. Bruce Robinson in the University of Western Australia Department of Medicine. My position was funded by James Hardie Industries and the Healy Research Foundation. I worked on the immunobiology of malignant mesothelioma, the roles of transforming growth factor-beta and interleukin-6, the mechanism of action of interferon-alpha immunotherapy, and the potential of antisense oligonucleotide therapy. My cosupervisory duties covered one research assistant and four students. This research contributed to clinical trials aimed at alleviating the paraneoplastic effects of this malignancy.

1990-91: In November 1989, my spouse, Dr. Helle Bielefeldt-Ohmann, and I secured research positions in Australia. I joined the Menzies School of Health Research in Darwin in June 1990 and was awarded an NH&MRC Australian Postdoctoral Fellowship. My research, overseen by Dr. Ian Gardner and Prof. John Mathews, showed that *Chlamydia trachomatis* binds to human monocytes, B cells and CD4 T cells, activating them to secrete cytokines including interleukin-6. My cosupervisory duties included three students involved in molecular, serological and epidemiological studies of infectious diseases in Aboriginal people. I view this as a "pro bono" period of work for the disadvantaged.

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1985-89: In September 1985, I began a PhD at the University of Saskatchewan in Canada, based at the affiliated Veterinary Infectious Disease Organisation. My co-mentors were Drs Lorne Babiuk and Tim Zamb. I completed the required coursework, for which I received the Commonwealth Bureau of Animal Health Prize, and in May 1986 began work on expression and characterization of bovine herpesvirus-1 (BHV-1) glycoproteins in transfected mammalian cells. My PhD thesis was defended and accepted in October 1989. During my PhD I also worked on bovine cytokines, other recombinant viral proteins, and development of vaccine vectors, and acted as a co-adviser for a number of graduate students. This work was academically and commercially productive via 14 publications and 4 patents.

1984-85: In April 1984, I joined a Commonwealth Serum Laboratories (CSL) and University of Melbourne joint research project on development of a bivalent EHV-1/4 vaccine. Master vaccine stocks were produced for tests of safety and efficacy in mice and horses. This vaccine has since been marketed as "Duvaxyn EHV1,4" or "FluVac EHV 4/1 Plus".

1982-84: In January 1982 I began a Master of Veterinary Science (research) degree at the University of Melbourne. Under the supervision of Dr. Michael Studdert, I studied the relationships between two "strains" of equine herpesvirus type-1 (EHV-1). Antibody and T cell responses of specific-pathogen-free foals, along with molecular studies of genomic DNA differences, contributed to the fundamental reclassification of EHV-1 into two viruses: EHV-1 and EHV-4.

Referees

Available on request.

END.